UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

PLAINTIFF'S RESPONSE TO PFIZER INC.'S MOTION FOR LEAVE TO INTERVENE FOR A LIMITED PURPOSE

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INTRODUCTION

The motion filed by Pfizer Inc. ("**Pfizer**") seeks leave for Pfizer to intervene for the limited purpose of ensuring "expeditious action" and to remain "informed of relevant developments." (Dkt. No. 40 at 2.) Plaintiff welcomes Pfizer's participation in this matter to the extent it will in fact expedite the release of the requested documents. However, it is what Pfizer has refused to say that concerns Plaintiff in consenting to the company's intervention without the Court providing, at the least, appropriate limitations to assure Pfizer does not cause delay or prejudice to Plaintiff.

Even though the FDA has more than sufficient resources to expeditiously produce the requested documents, and the agency has repeatedly stated its commitment to protecting Pfizer's interests, Pfizer could still assist the FDA with expediting release of the requested documents. Pfizer, however, provides no reason why it needs to intervene in this matter to render that purported assistance. Nor can Plaintiff discern why Pfizer needs to intervene in this matter to assist the FDA with expediting release of the requested documents – it can render this assistance without intervening. Indeed, Pfizer, for over a year now, has been "working closely with the FDA" regarding its Covid-19 vaccine and is already working with the FDA to identify, on or before February 1, 2022, all documents in its application that do not include trade secrets. Nor does Pfizer have any need now to intervene to protect any trade secrets because Plaintiff has not sought to challenge any redactions. If the Court has uncertainty as to whether Pfizer has stated an extant basis for intervening, Plaintiff respectfully requests that the Court ask Pfizer to clarify how intervening would assist in expediting release of the documents beyond what it could do to assist the FDA without intervening in this action.

Separately, in conferring with Pfizer's counsel prior to moving to intervene, Plaintiff sought confirmation that Pfizer would not seek to challenge the Court's January 6th order (Dkt.

No. 35) requiring the FDA to produce at a rate of 55,000 pages every 30 days. Nevertheless, even though Pfizer said it "does not presently intend to move the Court to reconsider its January 6, 2022 order," it refused to rule out such a challenge to the rate of production ordered by the Court, stating that it "is not in a position at this time to waive its ability to do so if circumstances change such that there is good cause at a later time to do so." (Dkt. No. 40 at 3.) The position taken by Pfizer on this issue casts doubt as to its claimed limited purpose to intervene to seek to expedite release of the underlying documents. Plaintiff is therefore concerned that its involvement will serve as another way for the FDA, now with assistance from Pfizer, to continue its campaign to delay production. Hence, to the extent Pfizer is permitted to intervene without limitation, such that it may seek to challenge orders entered in this action prior to its intervening, or to otherwise delay the Court-ordered production schedule, Plaintiff opposes Pfizer's motion as untimely.

On the other hand, if the Court concludes Pfizer intervening in this action will increase the rate of production beyond what the FDA could do if Pfizer were not granted leave to intervene, and Pfizer's involvement is limited to prevent delay or prejudice as set forth below, Plaintiff does not object to Pfizer intervening.

ARGUMENT

On January 21, 2022, Pfizer moved to intervene in this action pursuant to either Rule 24(a) or Rule 24(b). It claims that it made this motion for the stated "limited purpose of helping FDA and the Court ensure expeditious action as ordered by this Court and ensuring that Pfizer is informed of relevant developments in relation to the case." (Dkt. No. 40 at 2.) In doing so, the company explains that it "hopes that engaging in a dialogue with the Government where it has questions about Pfizer's view regarding certain portions of the BLA will make it easier for the

Government to meet the production schedule ordered by the Court." (*Id.*) However, Pfizer never explained why it needs to intervene in this action at this time in order to conduct that dialogue.

I. STANDARD FOR TIMELINESS UNDER RULE 24

One of the primary cases Pfizer relies on, *Sierra Club v. Espy*, 18 F.3d 1202 (5th Cir. 1994), warns that "[c]ourts should discourage premature intervention that wastes judicial resources." *Id.* at 1206. Rather, "[a] better gauge of promptness is the speed with which the would-be intervenor acted when it became aware that its interests would no longer be protected by the original parties." *Id.* In evaluating the timeliness of a motion to intervene, courts in the Fifth Circuit examine four considerations: "'(1) how long the putative intervenor knew, or reasonably should have known, of its stake in the action; (2) the prejudice, if any, the existing parties may suffer because the putative intervenor failed to intervene when it knew, or reasonably should have known, of its stake; (3) the prejudice, if any, the putative intervenor may suffer if intervention is not allowed; and (4) any unusual circumstances weighing in favor of, or against, finding timeliness.'" *Script Sec. Sols. LLC v. Logitech Inc.*, No. 216CV01400JRGRSP, 2017 WL 10242574, at *2 (E.D. Tex. Nov. 8, 2017) (quoting *Effjohn Int'l Cruise Hldgs., Inc. v. A&L Sales, Inc.*, 346 F.3d 552, 560–61 (5th Cir. 2003)).

The *Script Sec. Sols.* decision provides a relevant example where the court evaluated these four considerations. 2017 WL 10242574. There, by the time of the motion to intervene, the existing parties had established a schedule for evaluating the patent claims and the date to move to invalidate any claims had already passed. *Id.* at *2. Likewise, the parties had already commenced claims discovery, and a claims construction proceeding was planned for just a few months after the motion to intervene. *Id.* Under those circumstances, the court denied the motion to intervene. *Id.* at *1. It was concerned that the intervenor would seek to invalidate some of the patent claims and seek changes to the existing scheduling order, both of which would prejudice

the plaintiff. *Id.* at *2. Nevertheless, recognizing the intervenor's legitimate interest in the action, the court encouraged it to move for discretionary intervention pursuant to Rule 24(b), under which "the court may limit the scope of a movant's intervention to avoid undue delay and prejudice to the parties." *Id.* at *3. The court suggested that, in any such motion, the intervenor would have to agree "not … to move any … deadlines without the agreement of the parties, and … to be bound by all existing orders in this action." *Id.* (citing *Nikon Corp. v. ASM*, 222 F.R.D. 647, 651-52 (N.D. Cal. 2004) (permitting intervention under Rule 24(b) with certain limitations "so as to minimize delay and burdens to the parties and keep this case on track")); *see also New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 470-71 (5th Cir. 1984) ("Permissive intervention is wholly discretionary with the [district] court ... even though there is a common question of law or fact, or the requirements of Rule 24(b) are otherwise satisfied." (internal quotations omitted)).

II. PFIZER'S MOTION IS UNTIMELY IF THE COMPANY SEEKS TO ALTER THE EXISTING SCHEDULE

Like in *Script Sec. Sols.*, here, Plaintiff is concerned that Pfizer's intervention will unduly prejudice Plaintiff if the company seeks reconsideration of the production schedule established by the Court's order entered on January 6, 2022, or otherwise seeks to delay production by the FDA.

With this in mind, Plaintiff advised Pfizer's counsel as part of their meet-and-confer process that it "does not object to Pfizer moving to intervene, so long as Pfizer intends to only address decisions going forward and not to ask the Court to reconsider decisions it has already reached since any motion to intervene as to already adjudicated matters is untimely." (Dkt. No. 40 at 3.) Pfizer's refusal to agree to this limitation raised concerns for Plaintiff because it calls into question the company's alleged limited purpose for intervening in this action, which is purportedly to expedite release of the documents. (*Id.*)

As such, because Pfizer itself will not rule out the possibility, the Court should analyze the timeliness of the instant motion assuming there is at least the possibility that Pfizer will move to amend or delay the Court's existing schedule. Applying the four considerations noted above, it would be untimely for Pfizer to intervene in order to alter the Court's January 6th production schedule, and therefore, if the company is permitted to intervene, it must be limited by restrictions similar to those in *Script Sec. Sols.*

A. Consideration 1: Pfizer's Delay is Unreasonable if it Hopes to Alter the Production Schedule

Under the first consideration, Pfizer claims that it learned about this action "from news reports in connection with the December 14, 2021 Scheduling Conference." (Dkt. No. 41 p. 11.) Even though Pfizer is correct that only a little over five weeks elapsed between this supposed discovery and the instant motion, "[t]he timeliness inquiry 'is contextual; absolute measures of timelines should be ignored.'" *Wal–Mart Stores, Inc. v. Texas Alcoholic Beverage Commn.*, 834 F.3d 562, 565 (5th Cir. 2016) (cited by Pfizer) (quoting *Espy*, 18 F.3d at 1205). For instance, in *Wal–Mart Stores,* the Fifth Circuit did not look to the exact number of days in order to determine whether the motion was timely. *Id.* Rather, the Circuit found that the motion was timely because the intervenor "sought intervention before discovery progressed and because it did not seek to delay or reconsider phases of the litigation that had already concluded." *Id.*

In contrast to *Wal-Mart Stores*, Pfizer knew or should have known that Plaintiff was seeking an expedited production schedule, and that the Court intended to rule on that schedule quickly. In such circumstances, if Pfizer wanted to have input into the production schedule, it had more than 3 weeks between its purported discovery of the action and the Court's order on January 6, 2022, making its delay in filing this motion unreasonable if it hoped to have input into the production schedule.

B. Consideration 2: A Motion to Delay Production Would Prejudice the Existing Parties

The analysis of the second timeliness consideration plays out much as it did in *Script Sec. Sols.* If Pfizer wants to slow the production schedule in any way, that will be prejudicial to Plaintiff. As described in detail in Plaintiff's brief to the Court regarding the production schedule, there is an urgent need to have these documents produced in a quick and timely manner. Likewise, the FDA claims that since the January 6th order, it has moved heaven and earth to try to meet the deadlines set by that order. Setting aside whether this claim is true (a point called into serious question by Plaintiff's opposition papers regarding the FDA's motion to modify the schedule, Dkt. Nos. 44-45), a motion even in the next few weeks by Pfizer to further reconsider the production schedule will mean that much of the FDA's work in trying to meet the existing schedule may need to be changed. Thus, any effort by Pfizer to change the existing schedule will serve to prejudice both existing parties.

C. Consideration 3: Pfizer's Motion Fails to Establish What, if Any, Prejudice the Company Will Suffer if it's Current Motion is Denied

Pfizer's motion also fails to identify an extant reason to support the third consideration, *i.e.*, "the prejudice, if any, the putative intervenor may suffer." *Script Sec. Sols.*, 2017 WL 10242574, at *2.

As confirmed during the meet and confer, and as evidenced by the fact the FDA has already requested that Pfizer identify documents not containing trade secrets by February 1st, the agency and the company have already entered into a dialogue. Indeed, the FDA's regulations include provisions that specifically permit companies to engage with the FDA with regard to identifying trade secrets. 21 C.F.R. 20.61(d). Those regulations are particularly enlightening here because they include a timeline companies must meet in order to ensure that those companies' involvement

does not slow down the government's response to the FOIA request.[1] Thus, contrary to Pfizer's claims, even if it is not a party to this action, it is not prejudiced in its ability to engage with the FDA in order to expedite production and relay to the FDA what portions of the documents it believes require redaction.

Of course, if down the road Plaintiff chooses to challenge any redactions, Pfizer may have an interest then and could be prejudiced if not permitted to intervene. However, that has not happened yet, may never happen, and if it happens, will likely not happen for at least several months, and hence raises the question of why Pfizer needs to intervene at this stage of the litigation with regard to trade secrets. At the least, there should be some claim made in this action seeking to lift redactions for trade secrets before Pfizer's participation is necessary.

Pfizer vaguely claims "that Government entities generally cannot adequately represent the interests of aspiring intervenors[,]" thereby trying to justify its involvement by appearing to argue that the FDA will not protect its interests. (Dkt. No. 41 p. 13.) However, this argument contrasts sharply with the FDA's repeated attestations throughout this action that it takes very seriously its obligation to protect private citizen's data and Pfizer's trade secrets. If anything, the FDA put Pfizer's interests well ahead of the American public's interest when it originally sought to produce just 500 pages per month, in large measure to ensure it was protecting Pfizer's trade secrets and

[1] "A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 … The person may make this designation either **at the time the records are submitted** to the Government or **within a reasonable time thereafter**. 21 C.F.R. 20.61(d) (emphasis added). "When the [FDA] receives a request for such records and determines that disclosure may be required, the [FDA] will make reasonable efforts to notify the submitter … The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure…The submitter has **5 working days from receipt of the notice to object to disclosure of any part of the records** and to state all bases for its objections." 21 C.F.R. 20.61(e) (emphasis added).

confidential business information. (*E.g.,* Dkt. No. 22 p. 10 ("To ensure protection of this [confidential business and trade secret information of Pfizer], … FDA must carefully review and, if necessary, redact exempt information on a line-by-line basis.").) The FDA then reiterated that same strong desire to protect Pfizer's interests in its current motion to modify the production schedule. (*E.g.,* Dkt. No. 37 p. 10 ("while the agency recognizes the public interest in the public disclosure of the records here at issue, FDA must also ensure that the personal information of clinical trial participants, as well any trade secret or commercially confidential information contained within the records, is protected from disclosure").) Thus, especially with Pfizer now assisting the FDA, the interest Pfizer has in protecting its trade secrets does not require intervention.

The lack of a need for Pfizer to intervene, at least at this time before Plaintiff has moved to challenge any redactions, raises questions for Plaintiff, especially in light of Pfizer's refusal to rule out a challenge to the current schedule. Of course, in addition to Pfizer seeking to cause delay, there is another reason why Pfizer may be seeking to intervene, but which the company did not discuss outright because it does not support intervention. Pfizer may be seeking to intervene to protect its public relations image.

As Pfizer states in its brief, this action has received significant media attention. (Dkt. No. 41 p. 15 (referencing "news reports about this Scheduling Conference in December 2021").) Not all of that attention has been positive given the FDA's repeated attempts to delay production in order to avoid transparency. (Dkt. No. 44.) Therefore, it comes as no surprise that Pfizer's instant brief is littered with comments like: "Pfizer supports the public disclosure of the vast majority of this information, to promote transparency and the public's confidence in the vaccine" (Dkt. No. 40 at 1.) The company then spends a full page and a half of its brief citing documents to support

its claim that, "Pfizer, FDA, and others already have made public extensive data and information about the vaccine," all of which is otherwise irrelevant to its motion. (Dkt. No. 40 at 1.) In doing so, the company even includes a highly misleading header for another irrelevant list of studies, "Preprints of safety and efficacy data as they became available," which falsely indicates that these preprints include the underlying safety and efficacy data. (Dkt. No. 41 at 7.) Of course, none of these documents contain the raw data relied upon to license Pfizer's vaccine that is sought in this action, *i.e.*, the underlying data that would permit verifying any of the company's claims, but rather they contain only sanitized summaries of information. Pfizer may just be hoping that the next reporter does not look any closer than the headlines. At any rate, a company's desire to protect its public image is not the type of interest that the drafters of Rule 24 had in mind when they permitted third parties to intervene in court actions, especially because, as the page-and-a-half in Pfizer's brief shows, that desire conflicts with the very real need for judicial efficiency.

D. Consideration 4: The Unprecedented Urgency of this Matter Calls for Even Greater Caution when Evaluating the Timeliness of Intervention

The fourth timeliness consideration, "any unusual circumstances weighing in favor of, or against, finding timeliness" also plays an important role in this action. *Script Sec. Sols.*, 2017 WL 10242574, at *2. This Court recognized the unusual circumstances in its order when it acknowledged "the need for unprecedented urgency in processing this request[.]" (Dkt. No. 35 p. 3.) This matter concerns an issue of national importance, where "stale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). Thus, any delays now not only prejudice the parties as discussed above, but also prejudice the American public and its right to transparency when it comes to the unprecedented actions its government has taken during this pandemic, and in particular with regard to the product at issue – a product which has

been mandated while Pfizer has been given complete financial immunity by the government for any safety or efficacy issues with its product.

Nonetheless, Pfizer ends it brief by stating that, it "does not dispute that Plaintiff is entitled to non-exempt information from the BLA under its FOIA request and Pfizer does not seek any delay in the production of that information. Rather, Pfizer's intervention will facilitate production of the information Plaintiff seeks since Pfizer can assist the Parties in efficiently segregating and redacting any data and information that are subject to FOIA statutory exemptions." (Dkt. No. 41 at 15.) If that is all Pfizer truly seeks, then Plaintiff welcomes Pfizer's intervention for that limited specific purpose. However, for the reasons discussed above, Pfizer's refusal to rule out a request to change the production schedule, and its failure to articulate a convincing reason why it needs to intervene right now (rather than later if any redactions are challenged), concern Plaintiff.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully asks that the Court deny Pfizer's motion under Rule 24(a) as untimely under the circumstances and because its interests are already adequately represented by the FDA, but that it grant the motion under Rule 24(b) for the limited purpose of helping FDA and the Court ensure expeditious action as ordered by this Court with the following limitations similar to those imposed in the *Script Sec. Sols.* matter:

1. Pfizer is bound by all existing orders in this action;
2. Pfizer is prohibited from seeking to alter the January 6th order, or an amended schedule set forth in any order regarding FDA's pending motion to amend the January 6th order;
3. Pfizer is prohibited from engaging in conduct that is intended to delay production of the documents as ordered by the Court; and

4. Pfizer is directed to comply with the FDA's request for it to identify all documents that do not include trade secrets and confidential information by or before February 1, 2022.

Dated: January 25, 2022

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Gabrielle G. Palmer, CO Bar No. 48948
200 Park Avenue
17th Floor
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
gpalmer@sirillp.com

HOWIE LAW, PC
John Howie
Texas Bar Number: 24027239
2608 Hibernia Street
Dallas, Texas 75204
Tel: (214) 622-6340
jhowie@howielaw.net

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

On January 25, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all counsel and/or pro se parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

DATED: January 25, 2022

/s/ Aaron Siri

Aaron Siri
200 Park Avenue, 17th Floor
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com